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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,510	11/08/2001	Charles S. Schasteen	NVI 5183.1	9657

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SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,510	SCHASTEEN ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-30 and 113-166* is/are pending in the application.

4a) Of the above claim(s) *144 and 145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-30,113-116,118,119,136-143,146,148-150,153 and 154* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *4/5/06*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This Office action is responsive to Applicant's response filed February 6, 2006.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejections Maintained

3. The rejection is maintained for claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 under 35 U.S.C. 102(a) as anticipated by Conkle et al, for the reasons set forth on pages 3-10, paragraph 3 of the previous Office Action.

The rejection was on the grounds that Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8). Claim limitations such as "the composition ameliorates a decline or decrease in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as inherent and as a limitation of intended use. The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the

substrates lose their function. Such is not the case with the instantly claimed articles. The polypeptides of the claimed articles remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the claims are drawn to a composition which comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly *no functional relationship exists between the instructions for use and the composition*. Thus, the instructions on the package insert bears no patentable weight with regard to double patenting, 102, and 103 rejections. The claim limitation "wherein said oocysts have been separated by tangential flow filtration from an aqueous sporulation medium is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Conkle et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

A) Applicant urges that the claimed invention is structurally different from Conkle et al and Evans et al and not merely intended use.

B) Applicant urges that the extent of freedom from bacterial contaminants is expressed in product-by-process language because it has not been quantified and thus cannot be expressed in terms of numerically defined concentration. Applicant's urges that a structural limitation on bacterial contamination is expressly imposed by claimed 1. Applicant urges that a distinctive structural characteristic is imparted by the specified requirement of tangential flow filtration. Both the express substantial exclusion of bacterial contaminants which are present in said source and the product-by-process limitations impose structural limitation on the claims. Applicant urges that it is important to understand that bacterial contaminants as specified in claim 1 not only encompass live bacteria but non-viable contaminants such as dead bacteria and cellular debris that remain after treatment with an anti-bacterial agent. Applicant urges that treatment, according to Conkle et al, may be effective in treating bacteria but Conkle et al fail to teach or suggest removal of non-viable bacteria and bacteria debris whether by tangential flow or otherwise. Applicant urges as specified in claim 1 since the pore size

of the filter membrane used during tangential flow filtration is large enough to allow bacteria to pass through, the oocysts retained by the filter membrane have been separated from both viable and non-viable contaminants such as bacteria and cellular debris. Applicant urges that Conkle et al do not teach the use of a filter pore size small enough to prevent sporulated oocysts from entering the pores but large enough to allow bacteria to pass through the pores. Applicant urges that the washing steps of Conkle et al do not render the composition of Conkle et al "substantially free of bacterial contaminants". Applicant urges that there is no statement or suggestion of desirability of separating the oocysts from bacterial or any other contaminants.

C) Applicant urges that the Examiner states in the previous Office action that Conkle et al teach purified suspensions. Applicant urges that Conkle et al offers no explanation as to what constitutes "purified suspensions. Applicant urges that the composition of Conkle et al can be said to comprise a greater amount of non-viable contaminants than the compositions of claim 1. Applicant refers the Examiner to section 2144 of the MPEP which states that "pure materials are novel vis-à-vis less pure or impure material because there is a difference between pure and impure materials. Therefore the issue is whether claims to a pure material are unobvious over the prior art". Applicant urges that pure material are different from less pure or impure materials.

D) Applicant urges that the Office action does not contain an express objection over Conkle et al alone but it continues to make arguments that relate to obviousness under 103 rather novelty under 102. Applicant urges that the Examiner has neither entered a rejection under 103(a) based on Conkle et al nor offered an basis for prima facie obviousness of a coccidiosis vaccine which is substantially free of bacterial contaminants. Applicant urges in the absence of prima facie obviousness, there is no burden on Applicant to offer secondary evidence of any sort, whether commercial success, failure of others, unexpected properties or otherwise. Applicant also argues unexpected results as well as hindsight reconstruction. Applicant also argues that claim 1 is patentable over Conkle et al under 102 and 103. Applicant urges that since claims 4-10, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150 and 153-154 depend from claim 1 then these claims are patentable over Conkle et al.

E) Applicant urges that claim 113 is directed to a kit comprising the composition of claim 1 and instructions for administration of the composition to an animal and this claim has been amended. Applicant urges that instructions in the kit constitute more than intended use.

F) Applicant urges that instructions are functionally related to the composition and therefore should be given patentable weight. Applicant urges that "a ratio defined by the minimum immunizing dose" and "amount determined by storage half-life determinations" are more than intended use and it cannot be found inherently in Conkle et al (claim 139).

Examiner's Response to Applicant's Argument

Applicant's arguments filed February 6, 2006 have been fully considered but they are not persuasive.

A) It is the Examiner's position that the claimed composition and the composition of the prior art are not structurally different. The claims are directed to a composition comprising viable sporulated oocysts (a product). The claims require that the composition comprises "sporulated oocysts" wherein the oocysts are at least about 10,000 oocysts per milliliter and wherein the composition is sterile and contains less than about 0.4% of alkali metal dichromate. Claim limitations such as "said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing" and "said oocysts and bacterial contamination using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but said bacterial contaminants can pass through the pores" are process limitations. The compositions taught by Conkle et al are the same as the claimed invention because

they comprise 1) sporulated oocysts, 2) the oocysts are at least about 10,000 oocysts per milliliter and 3) the composition is sterile and contains less than about 0.4% of alkali metal dichromate.

B) It is the Examiner's position that Applicant is arguing process limitations in a product claim. MPEP 2113 discloses that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. **The patentability of a product does not depend on its method of production.** If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Therefore, one of skill in the art would reasonably conclude that the patentability of the product is based on the product itself.

To address Applicant's comments regarding process limitations such as removal of bacterial contaminants, the use of tangential flow filtration and the used of filter membranes with specific pore sizes (which includes the limitations in claims 153-154), it should be remembered that the purification or production of a product by a particular process does not impart novelty to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In

re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

It should be noted that the Examiner disagrees with Applicant's assertion that " the prior art does not disclose separating the oocysts from bacterial or other contaminants that may be present in the sporulation medium or in the bleached oocysts suspension". It should be noted that in this response Applicant admits that "Conkle et al state that oocysts may be washed following sporulation to reduce the residual oxidant concentration to an acceptable level and serial washings maybe conducted preferably by membrane filtration or by diafiltration". This process as disclosed by Conkle et al teach the removal of contaminants from the suspension comprising the oocysts.

C) To address Applicant's comments regarding purified suspension, it should be noted that the well accepted meaning for the term "purify" or "purified" means "to clear from material defilement or imperfection or to rid unwanted contaminants". Therefore, the prior art does teach the removal of unwanted contaminants.

To address Applicant's argument regarding section 2144 of the MPEP, it should be noted that this section of the MPEP focuses on rationale for supporting a 103(a) rejection. It should be remembered that Conkle et al was applied in this art rejection as an anticipatory reference as set forth under 35 U.S.C. 102 and not 35 U.S.C. 103.

D) To address Applicant's arguments regarding a 103(a) rejection over Conkle et al, it should be noted that the Examiner agrees with Applicant the no such rejection had been made of record. The Examiner disagrees with Applicant's assertion that the Office has made arguments that relate to obviousness rather than novelty. The rejection is made under 35 U.S.C. 102 instead of 35 U.S.C. 103 because the claims are directed to a product and not a process of making the product. It should be remembered that the patentability of the product is based on the product itself. To address Applicant's comment related to unexpected results, as stated above there is no rejection of record of under 35 U.S.C. 103(a) over Conkle et al alone. Therefore, Applicant's arguments and comments regarding this issue are irrelevant.

E) To address Applicant's comments regarding a kit, it should be noted that the kit as set forth in claim 113 comprises the composition of claim 1 and instructions for the administration of said composition to an animal. It should be noted that the instructions as to how to use the kit is a limitation of intended use and has no functional

relatedness to the composition.

F) To address Applicant's comment's regarding, "... a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" would be inherent in the teachings of the prior art because Conkle et al teach that encysted protozoa oocysts including *Eimeria maxima, E. mitis, E. tenella, E. acevulina, E. brumetti, E. necatrix, E. praecox* and mixtures thereof including multiple strains can be give in a single vaccine. Vaccines are known as pharmaceutical compositions that are used to immunize subjects and are thereby given in immunizing doses and can include determination by storage half-life determinations. Therefore, this claim limitation is met by the prior art. It is the position of the Examiner that Conkle et al anticipate the claimed composition.

Applicant has provided no evidence that the claimed composition differs from that of the prior art. Applicant has provided no side-by-side comparison to show that the claimed compositions differs from that of the prior art. Although, the claimed limitation "for the prevention or control of coccidiosis" is the intended use of the claimed invention, it should also be noted that the composition of the prior art is used for the same purpose as the claimed invention.

4. The rejection is maintained for claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148, 149-150 and 153-154 under 35 U.S.C. 103(a) as unpatentable over Conkle et al in view of Brown et al for the reasons set forth on pages 10-13, paragraph 4 of the previous Office Action.

The rejection was on the grounds that Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8).

Conkle et al do not teach the use of *Propionibacterium acnes.*

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as day one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14). Claim limitations such as, "a kit", "the composition ameliorates a decline in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as limitations of intended use. The claims limitation "wherein said composition contains at least about 30 milligrams (dry weight of *P. acnes* per milliliter is being viewed as a limitation of optimizing experimental parameters since Brown et al teach that other initial concentrations of *P. acnes* suspension are within the scope of the invention because the actual administration to the chick is adjusted and diluted for optimum dosages (column 4, lines 19-22). The claim limitation "wherein said oocysts have been separated by tangential flow filtration from an aqueous sporulation medium is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased

purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the compositions comprising oocysts from the genus *Eimeria* of Conkle et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as day one or even *in ovo* and to combat coccidiosis and other poultry diseases. It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts, a diluent, a buffer and a bactericide would be effective in preventing coccidiosis in animals.

Applicant's Arguments

A) Applicant urges that other than the disclosure of *P. acnes,* Brown et al adds nothing to the teachings of Conkle et al. Applicant urges that the claimed invention is patentable over Conkle et al alone and any combination of Conkle et al and Brown et al. Applicant urges that the recitation of "bacterial contaminants which are present in said source" and the product-by-process limitations in claim 1 impose structural limitations on the claim to distinguish it from the prior art.

B) Applicant urges that there is no motivation to modify the cited references since there is no disclosure or suggestion in the prior art to arrive at a composition comprising oocysts that are substantially free of bacterial contaminants which have been separated by tangential flow filtration having a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but the bacterial contaminants can

pass through the pores. Applicant urges that there is no statement or suggestion of desirability of separating the oocysts from bacterial or any other contaminants.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed February 6, 2006 have been fully considered but they are not persuasive.

A) As stated above, it is the Examiner's position that the claimed compositions and the compositions as set forth in the combination of prior art teachings are not structurally different. The claims are directed to composition comprising viable sporulated oocysts (a product). The claims require that the composition comprise: : 1) "sporulated oocysts", 2) wherein the oocysts are at least about 10,000 oocysts per milliliter and 3) wherein the composition is sterile and contains less than about 0.4% of alkali metal dichromate. Claim limitations such as "said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said oocysts" and "bacterial contamination using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but said bacterial contaminants can pass through the pores" are process limitations. The combination of prior art teachings (Conkle et al and Brown et al) teach the claimed invention because Conkle et al teach compositions comprising: 1) sporulated oocysts, 2) the oocysts are at least about 10,000 oocysts per milliliter and 3) the composition is sterile and contains less than about 0.4% of alkali metal dichromate and Brown et al teach that *Propionibacterium acnes* can be used for stimulating non-specific cell

mediated immune responses in poultry at an age as early as day one or even *in ovo* and to combat coccidiosis and other poultry diseases. The combination of references teach the claimed invention.

B) In response to applicant's argument that there is no motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Conkle et al teach compositions comprising oocysts (page 4). Conkle et al do not teach *Propionibacterium acnes*. However, Brown et al teach compositions comprising *P. acnes*. One of ordinary skill in the art would be motivated to add the *P. acnes* compositions as taught by Brown et al to the compositions comprising sporulated oocysts of Conkle et al because Brown et al teach *Propionibacterium acnes* is an immunostimulant for providing non-specific cell-mediated immune response in poultry (column 3). One of ordinary skill in the art would expect a reasonable expectation of success in using the compositions of Brown et al and Conkle et al as combined because Brown et al teach that *P. acnes* can be used to combat coccidiosis at an age as early as one or even *in ovo* and other poultry diseases and Conkle et al teach that

the sporulated oocysts of the invention can be formulated into a vaccine against avian coccidiosis.

To address Applicants comments regarding tangential flow and pore size, these limitation are process limitations. It should be remembered that the claims are drawn to product. It should be further remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. The claims are not patentable over the cited prior art. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

5. The rejection is maintained for claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 under 35 U.S.C. 102(b) as anticipated by Evans et al for the reasons set forth on pages 14-18, paragraph 5 of the previous Office Action.

The rejections was on the grounds that Evans et al teach compositions comprising sporulated oocysts derived form an oocysts an oocysts source comprising bacterial contamination (pages 5-6). Evans et al teach that sporulated oocysts concentration is 10^4(page 9). Evan et al teach that oocysts can of the invention can be treated with sodium hypochlorite and then sporulated (page 5). Evans et al teach that potassium dichromate is removed from the suspension by repeated washing of the oocysts(page 6), therefore the claim limitation , "...less than about 0.4% by weight of alkali metal dichromate" is taught by the prior art. Although Evans et al teach that the oocysts of the invention can be prepared by any of several methods known to the skilled artisan (page 5), claim limitations such as "... said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores "are being viewed as process limitations. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The

purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

Claim limitations such as "the composition ameliorates a decline or decrease in post-challenge performance", "kit for prevention or control of coccidiosis" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as a limitation of intended use.

The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed compositions. The compositions remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the

intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the claims are drawn to a composition comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly no functional relationship exists between the instructions for use and the composition. Thus, the instructions on the package insert bears no patentable weight with regard to double patenting, 102, and 103 rejections. Evans et al anticipate the claimed invention.

Applicant's Arguments

A) Applicant urges Evans et al do not disclose, either expressly or inherently each and every element of claim 1. Applicant urges that the claim limitation "exclusion of bacterial contaminants which are present in said source which is a product-by-process limitation impose structural limitations on the claim to distinguish it from the cited reference.

B) Applicant urges that repeated washings as taught by Evans et al do not remove the potassium dichromate form the oocysts suspension. Applicant urges that Evans et al do not disclose the use of tangential flow filtration much less the use of filter pore sizes small enough to prevent sporulated oocysts form entering the pores but large enough to allow bacteria to pass through. Applicant urges that there is no teaching or suggestion of the desirability of separating the oocysts form non-viable bacterial or other contaminants that may be present in the oocysts suspension.

C) Applicant urges that Evans et al do not disclose a composition comprising viable sporulated oocysts in an amount of at least about 10,000 oocysts per milliliter and less than about 0.4% by weight of alkali metal dichromate.

Examiner's Response to Applicant's Argument

Applicant's arguments filed February 6, 2006 have been fully considered but they are not persuasive.

A) It is the Examiner's position that the claimed composition and the composition of the prior art are not structurally different. The claims are directed to composition comprising viable sporulated oocysts (a product). The claims require that the composition comprises "sporuulated oocysts" where the oocysts are at least about 10,000 oocysts per milliliter and less than about 0.4% of alkali metal dichromate, said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said oocysts and bacterial contamination using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but said bacterial contaminants can pass through the pores" are process limitations. Evans et al teach compositions comprising sporulated oocysts (see page 9).

B) It is the Examiner's position that Applicant is arguing process limitations in a product claim. MPEP 2113 discloses that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. **The patentability of a product does not depend on its method of production.** If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Therefore, one of skill in the art would reasonably conclude that the patentability of the product is based on the product itself.

To address Applicant's comments regarding process limitations such as removal of bacterial contaminants, the use of tangential flow filtration and the used of filter membranes with specific pore sizes (which includes the limitations in claims 153-154), it should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant

increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

It should be noted that the Examiner disagrees with Applicant's assertion that "the prior art does not disclose separating the oocysts from bacterial or other contaminants that may be present in the sporulation medium or in the bleached oocysts suspension". Evans et al teach the removal of contaminants from the suspension comprising the oocysts. See page 7.

C) To address Applicant's comments regarding the amount of oocysts in the composition of the prior art, it should be noted that Evans et al teach preparations comprising 10^4 oocysts, (page 9), which is at least 10,000 oocysts/milliliter.

Applicant has provided no evidence that the claimed composition differs from that of the prior art. Applicant has provided no side-by-side comparison to show that the claimed compositions differs from that of the prior art. Although, the claimed limitation "for the prevention or control of coccidiosis" is the intended use of the claimed invention, it should also be noted that the composition of the prior art is used for the same purpose as the claimed invention.

6. The rejection is maintained for claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148 -150 and 153-154 under 35 U.S.C. 103(a) as unpatentable over Evans et al in view of Brown et al for the reasons set forth on pages 18-21, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Evans et al teach compositions comprising sporulated oocysts derived form an oocysts an oocysts source comprising bacterial contamination (pages 5-6). Evans et al teach sporulated oocysts concentration of 10^4 (page 9). Evan et al teach that oocysts can of the invention can be treated with sodium hypochlorite and then sporulated (page 5). Evans et al teach that potassium dichromate is removed from the suspension by repeated washing of the oocysts(page 6), therefore the claim limitation , "...less than about 0.4% by weight of alkali metal dichromate" is taught by the prior art.

Evans et al do not teach the use of *Propionibacterium acnes*.

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as day one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14). Claim limitations such as "the composition ameliorates a decline in post-challenge performance", kit for the prevention or control of coccidiosis comprising instructions for administration of said composition to an animal" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as a limitation of intended use. Although Evans et al teach that the oocysts of the invention can be prepared by any of several methods known to the skilled artisan (page 5), claim limitations such as "... said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores "are being viewed as process limitations.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the coccidiosis vaccines comprising oocysts of Evans et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as day one or even *in ovo* and to combat coccidiosis and other poultry diseases and Evans et al teach that vaccine compositions comprising *Eimeria* oocysts are effective at

vaccinating poultry against coccidiosis (see the Abstract). It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts and *Propionibacterium acnes* would be effective in preventing coccidiosis in animals.

Applicant's Arguments

A) Applicant urges that other than the disclosure of *P. acnes* Brown et al adds nothing to the teachings of Evans et al. Applicant urges that the claimed invention is patentable over Evans et al alone and any combination of Evans et al and Brown et al. Applicant urges that the recitation of "bacterial contaminants which are present in said source" and the product-by-process limitations in claim 1 impose structural limitations on the claim to distinguish it from the prior art.

B) Applicant urges that there is no motivation to modify the cited references since there is no disclosure or suggestion in the prior art to arrive at a composition comprising oocysts that are substantially free of bacterial contaminants which have been separated by tangential flow filtration having a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but the bacterial contaminants can pass through the pores. Applicant urges that there is no statement or suggestion of desirability of separating the oocysts from bacterial or any other contaminants.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed February 6, 2006 have been fully considered but they are not persuasive.

A) As stated above, it is the Examiner's position that the claimed composition and the composition of the prior art are not structurally different. The claims are directed to composition comprising viable sporulated oocysts (a product). The claims require that the composition comprises "sporulated oocysts" where the oocysts are at least about 10,000 oocysts per milliliter and less than about 0.4% of alkali metal dichromate, said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said oocysts and bacterial contamination using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but said bacterial contaminants can pass through the pores" are process limitations. The combination of prior art teachings (Evans et al and Brown et al) teach the claimed invention.

B) In response to applicant's argument that there is no motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Evans et al teach compositions comprising oocysts (page 9). Evans et al do not teach *Propionibacterium acnes*. However, Brown et al teach compositions comprising *P. acnes*. One of ordinary skill in the art would be motivated to add the *P. acnes* compositions as taught by Brown et al to the compositions comprising sporulated oocysts of Evans et al because Brown et al teach that *Propionibacterium acnes* is an immunostimulant for providing non-specific cell-mediated immune response in poultry (column 3). One of ordinary skill in the art would expect a reasonable expectation of success in using the compositions of Brown et al and Evans et al as combined because Brown et al teach that *P. acnes* can be used to combat coccidiosis at an age as early as day one or even *in ovo* and other poultry diseases and Conkle et al teach that the sporulated oocysts of the invention can be formulated into a vaccine against avian coccidiosis.

To address Applicants comments regarding tangential flow and pore size, these limitation are process limitations. It should be remembered that the claims are drawn to product. It should be further remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. The claims are not patentable over the cited prior art. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

Status of Claims

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
June 1, 2006

NITA MINNIFIELD
PRIMARY EXAMINER